UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,527	01/29/2004	Itai Bab	31949-200571	2819

26694 7590 05/30/2007

VENABLE LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	**PAPER NUMBER**
1651	
MAIL DATE	**DELIVERY MODE**
05/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,527	BAB ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28 and 30-48* is/are pending in the application.

4a) Of the above claim(s) *5-7,25 and 38-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8-24,26-28,30-37 and 46-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/28/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 2/28/07 to claims 1, 4-9, 13, 15, 16, 20, 21, 23, 25, 26, 28, 30, 37, 38, 46, and 48 have been entered. Claim 29 has been cancelled. Claims 1-28 and 30-48 remain pending in the current application. Claims 5-7 and 38-45 remain withdrawn from consideration at this time. Prior art references not included with this Office action can be found in a prior action. It is noted for the record that claim 13 is amended, not "original" as indicated on the claim listing.

Election/Restrictions

Claim 25 as currently amended is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: It is drawn to an *in vitro* method using cultured cells, while examination until this point has been limited to *in vivo* administration of oligopeptides. Claim 25 as currently drafted would have been included in Group II of the 9/7/06 restriction requirement had it been included at that time. The reasons set forth for distinction between Groups I and II in the 9/7/06 restriction are still applicable, for example that the claims do not share starting materials, process steps, or end points (see page 3 of the 9/7/06 restriction requirement).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 25 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Examination on the merits will continue on claims 1-4, 8-24, 26-28, 30-37, and 46-48 ONLY, to the extent they read on the elected species where applicable. Applicant's election without traverse of the species "Tyr-Gly-Phe-Gly-Gly (SEQ ID NO:1)" in the reply filed on 6/29/06 is still in effect over these claims. Claims 5-7, 25, and 38-45 are/remain withdrawn from consideration at this time.

Claim Rejections - 35 USC § 102

The rejections of record under 35 U.S.C. § 102 are withdrawn unless specifically addressed below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8, 10, 12-17, 19-21, 26-29, 31-37, and 46-48 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bab et al. (1995, WO 95/00166; 1/29/04 IDS reference AC). The claims are interpreted for this rejection only as being drawn to various methods comprising administering a peptide with the sequence Tyr-Gly-Phe-Gly-Gly (SEQ ID NO:1; "YGFGG") to a subject or exposing cells to YGFGG. In some dependent claims, the subject has undergone or is undergoing irradiation or has a hematological condition.

Bab et al. teach administering YGFGG in phosphate buffered saline (PBS) to mice once a day for twelve days; on day 8, the mice were treated with a single X-ray

radiation, and on day 14, the mice were sacrificed and their bone marrow isolated into PBS (Example 2; page 14, lines 7-26). Bab et al. further teach that the administration of YGFGG to mice stimulated the production of bone marrow cells (page 14, line 29, through page 15, line 5).

The discovery of a new use for an old structure based on unknown properties of the structure *might* be patentable to the discoverer as a process of using. *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) and *In re Tomlinson*, 363 F.2d 928, 150 USPQ 623 (CCPA 1966). See M.P.E.P. § 2112.02.

Bab et al. teach administering YGFGG to mice (Example 2). While Bab et al. do not teach all of the effects recited in claims 1, 8, 13, 15, 19, 25, 26, 28, 29, 30, 37, 46, and 48, they do perform the same administration of YGFGG as in the present application (Examples 1, 3, and 4; paragraphs 00157, 00159, and 00160). Because the method steps (i.e. administration of YGFGG, which is termed "OGP(10-14)" in the instant application) are the same, Bab et al. inherently teach the same effects as those recited in claims 1, 8, 13, 15, 19, 25, 26, 28, 29, 30, 37, 46, and 48. Bab et al. therefore anticipates the effects recited in claims 1, 8, 13, 15, 19, 25, 26, 28, 29, 30, 37, 46, and 48 as instantly claimed.

To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim. See *Standard Havens Prods., Inc. v.*

Gencor Indus., Inc., 953 F.2d 1360, 1369, 21 USPQ2d 1321, 1328 (Fed. Cir. 1991). However, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. See *id.* and *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 630, 2 USPQ2d 1051,1053 (Fed. Cir. 1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See *In re King*, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). **Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art.** See *Titanium Metals*, 778 F.2d at 780. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See *id.* at 782. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See *id.* at 782 ("Congress has not seen fit to permit the patenting of an old [composition], known to others..., by one who has discovered its...useful properties."); *Verdegaal Bros.*, 814 F.2d at 633.

This court's decision in *Titanium Metals* illustrates these principles. See *Titanium Metals*, 778 F.2d at 775. In *Titanium Metals*, the patent applicants sought a patent for a titanium alloy containing various ranges of nickel, molybdenum, iron, and titanium. The claims also required that the alloy be "characterized by good corrosion resistance in hot brine environments." *Titanium Metals*, 778 F.2d at 776. A prior art reference disclosed a titanium alloy falling within the claimed ranges, but did not disclose any corrosion-resistant properties. This court affirmed a decision of the PTO

Board of Appeals finding the claimed invention unpatentable as anticipated. This court concluded that the claimed alloy was not novel, noting, "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties." *Id.* at 782. This same reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle." See *Atlas Powder Co. v. IRECO Inc.*, 51 USPQ2d 1943 (Fed. Cir. 1999).

Thus, a reference may be anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently. A reference includes an inherent characteristic if that characteristic is the natural result flowing from the reference's explicitly explicated limitations. *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

In the instant case, the effects recited in claims 1, 8, 13, 15, 19, 25, 26, 28, 29, 30, 37, 46, and 48 flow from the administration of YGFGG to mice. The fact that Bab et al. did not necessarily recognize each and every effect of said administration does not render the administration itself patentable.

Furthermore, Bab et al. anticipates claims 2, 3, 12, 14, 27, 31-36, and 47 because these dependent claims do not further limit the steps recited within their respective independent claims *per se*, but rather describe effects of the steps. Therefore

Bab et al. anticipates these effects for the reasons discussed above. Claims 19, 25, 26, and 29 require "exposing" cells to YGFGG, which is anticipated by the administration to mice taught by Bab et al. because the term "exposing" does not particularly limit the manner in which the cells and the peptide interact, if at all. The term "exposing" does not, for example, require that the cells be cultured *in vitro* and contacted directly with YGFGG. Claims 9 and 30 require that the subject be undergoing irradiation; on day 8 of the method of Bab et al., the mice both irradiated and injected with YGFGG. Claims 20 and 21 require that the subject be suffering from a hematological disorder; this aspect is anticipated by the irradiated mice of Bab et al., which display low numbers of bone marrow cells (page 15, lines 1-2). Claim 28 requires obtaining "a sufficient amount" of stem cells from the treated subject, but since the claim does not particularly define any criteria for including a particular number of cells and excluding another or a requirement that the stem cells be purified to homogeneity, this claim is anticipated by the bone marrow isolation of Bab et al. (page 14, lines 22-23).

Response to Arguments

Applicants allege that Bab is non-enabling (Remarks, pages 11-14, 17, and 18), especially for subjects with hematological disorders or those undergoing chemotherapy (page 11). Applicants allege that Bab is silent as to enhancement of mobility of a particular type of stem cell (pages 12-14, 16, and 17). Applicants discuss at length the state of the hematopoietic stem cell mobilization art (pages 14-16), citing evidence that IL-3 increases proliferation of hematopoietic stem cells but not mobilization (pages 18-19). Applicants allege that the claimed effect would not have been predicted to be

yielded by the method of Bab at the time of the invention (page 19 and arguments in general). These arguments have been fully considered, but they are not persuasive.

When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. See *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980) and M.P.E.P. § 2121. In this case, Bab teaches exactly the same steps as those claimed by applicant, *i.e.* the administration of YGFGG oligopeptide to patients receiving irradiation (note that claim 1, for example, allows that the patient may be receiving irradiation but not necessarily chemotherapy). Whether Bab predicted or could have predicted each and every effect of their exemplified administration step is not a factor in determining whether Bab is enabling for that administration step. Methods are defined by their constituent steps; Bab teaches an administration step identical to the claimed administration step, and Bab performs the administration step on patients encompassed by the instantly claimed methods. The basis for applicant's allegation that Bab provides insufficient guidance for the person of ordinary skill in the art to practice the administration step on this patient set is simply not clear.

The majority of applicants' arguments regard whether the claimed effects are truly inherent effects of the recited YGFGG administration step. Applicants have presented no evidence that administering YGFGG as directed by Bab would not result in the claimed outcome. As discussed at length above, an inherent feature of an invention need not be recognized at the time of the invention. See M.P.E.P. § 2112. In

In re Schreiber, 128 F.3d 1473, 44 USPQ2d 1429 (Fed. Cir. 1997), the court affirmed a finding that a prior patent to a conical spout used primarily to dispense oil from an oil can inherently performed the functions recited in applicant's claim to a conical container top for dispensing popped popcorn. The examiner had asserted inherency based on the structural similarity between the patented spout and applicant's disclosed top, i.e., both structures had the same general shape. In this case, the patient set (*i.e.*, subjects receiving irradiation) and the administration step (*i.e.*, administration of YGFGG oligopeptide) taught in Bab are identical to the patient set and administration step as claimed; therefore, all outcomes of this administration step on the patient set are inherent outcomes, whether or not they were recognized by Bab at the time. Applicants have not amended the claims to distinguish their patient set or administration step from that of Bab; such an amendment might overcome this ground of rejection.

Regarding applicants' allegation that Bab does not teach mobilizing a particular subset of cells, the claims are not so limiting. All that is required in the claims is that "multilineage hematopoietic stem cells" with particular markers (claims 1-3), "early CD34-positive stem cells" (claim 8), "CD34 positive hematopoietic stem cells" with particular markers (claims 13-14), "BFU-E and GFMM CFUs" (claims 15 and 19), "hematopoietic CD34 positive cell stem cells" (claim 26), "hematopoietic stem cells" (claim 28), "circulating stem cells" (claim 30), and "circulating hematopoietic stem cells" (claim 48). Claims 21, 23, 37, and 46 merely require "treating" and does not recite any cell mobilization at all. Furthermore, the methods "comprise" the administration of YGFGG and therefore do not rule out the inclusion of additional administration steps

that might mobilize other cell types. Applicant is arguing limitations not recited in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claims 19, 26-28, and 46-48 remain rejected under 35 U.S.C. 102(a) as being anticipated by Chen et al. (2000, *Journal of Peptide Research* 56: 147-156; reference AD on 1/29/04 IDS).

Chen et al. teach administering YGFGG ("OGP(10-14)") in phosphate buffered saline (PBS) to mice (page 155, column 1).

Furthermore, Chen et al. anticipates claims 27and 47 because these dependent claims do not further limit the steps recited within their respective independent claims *per se*, but rather describe effects of the steps. Therefore Bab et al. anticipates these effects for the reasons discussed above. Claims 19 and 26 require "exposing" cells to YGFGG, which is anticipated by the administration to mice taught by Bab et al. because the term "exposing" does not particularly limit the manner in which the cells and the peptide interact, if at all. The term "exposing" does not, for example, require that the cells be cultured *in vitro* and contacted directly with YGFGG.

Response to Arguments

Applicants allege that the mice of Chen are not undergoing irradiation, chemotherapy, or transplantation (Reply, page 22). Applicants allege that Chen does not predict the effect of administered YGFGG on a specific subset of hematopoietic

stem cells (page 22). Applicants allege that the arguments against the rejection over Bab also apply to this rejection (page 22). These arguments have been fully considered, but they are not persuasive.

To be clear, this rejection is maintained over claims 19, 26-28, and 46-48 ONLY. None of these claims requires that the method be performed on a subject undergoing radiation, chemotherapy, or transplantation or on a subject suffering from a hematological disorder. All that is required is the administration of YGFGG to cells (claim 19) or to a donor (claim 28) or to a mammal (claim 46) or to a subject (claim 48). Applicant is arguing limitations not recited in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The discussion of the inherent effects of the method of Bab, above, also applies to applicants' arguments as to the inherent effects of the administration of YGFGG taught by Chen. The patient set and administration step taught by Chen is identical to those recited in the claims; as such, all effects of performing said administration step on said patient set are inherent.

Claim 19 remains rejected under 35 U.S.C. 102(b) as being anticipated by Gurevitch et al. (1996, *Blood* 88: 4719-4724; reference A31 on 8/20/04 IDS) taken in light of Bab et al. (1999, *Journal of Peptide Research* 54: 408-414; reference A12 on 8/20/04 IDS).

Gurevitch et al. teach administering OGP in phosphate buffered saline (PBS) to mice once a day for twelve days; on day 8, the mice were treated with a single myeloablative X-ray irradiation, and on day 14, the mice were sacrificed and their bone marrow isolated into PBS (page 4720, column 1). Gurevitch et al. further teach that the administration of OGP to mice stimulated the production of bone marrow cells (Table 3; Figure 1). Bab et al. (1999) is cited as evidence that OGP has the sequence ALKRQGRTLYGFGG (page 409, column 1, paragraph 2).

It is noted that claim 19 requires administration of "an oligopeptide **comprising** the amino acid sequence of [YGFGG]." The transitional term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, *e.g.*, *Invitrogen Corp. v. Biocrest Mfg.*, L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003). See M.P.E.P. §2111.03. In this case, the specification describes both an oligopeptide comprising the elected YGFGG species (for example, at page 5, paragraph 0009) and a short peptide consisting of the YGFGG sequence (for example, at page 5, paragraph 0010).

The discussion of inherent disclosure as applied to Bab et al. (WO 95/00166) also applies to this ground of rejection for the same reasons as discussed above.

Response to Arguments

Applicants allege that the claim has been limited to administering an oligopeptide consisting of YGFGG (Reply, page 22). Applicants allege that the arguments against the rejection based on inherency over Bab also apply to this rejection (pages 22-23). These arguments have been fully considered, but they are not persuasive.

It is noted for the record that claim 19 has not been amended. The scope of the oligopeptide is broader than "an oligopeptide consisting of YGFGG."

The discussion of the inherent effects of the method of Bab, above, also applies to applicants' arguments as to the inherent effects of the administration of YGFGG taught by Gurevitch. The patient set and administration step taught by Gurevitch is identical to those recited in the claims; as such, all effects of performing said administration step on said patient set are inherent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8, 11, 15, 18, 20, and 22-24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bab et al. (WO 95/00166) taken in view of Takayama et al. (1999, U.S. Patent 5,910,303).

The teachings of Bab et al. are relied upon as discussed above. Bab et al. do not teach treating myeloproliferative disorders or specifically increasing circulating early CD34+ stem cells or colony forming units (CFUs) in subjects with myeloproliferative disorders.

Takayama et al. teach treating myeloproliferative disorders, including myelofibrosis, with an agent that promotes platelet and leukocyte production and reversing the damage to bone marrow caused by radiation therapy (column 12, Examples 1 and 2).

A person of ordinary skill in the art would have had a reasonable expectation of success in treating myeloproliferative disorders, including myelofibrosis, with the YGFGG of Bab et al. because Bab et al. teach that YGFGG stimulates bone marrow cell production and subsequent repopulation of the immune system (page 14, line 29, through page 15, line 5). The skilled artisan would have been motivated to so modify the invention for the expected benefit of treating myelofibrosis in a patient.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to treat myeloproliferative disorders, including myelofibrosis, with the YGFGG of Bab et al. because Bab et al. teach that YGFGG stimulates repopulation of the immune system and because Takayama et al. teach that such repopulation treats myeloproliferative disorders, including myelofibrosis.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Claims 8, 11, 15, 18, 20, and 22-24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gurevitch et al. taken in view of Bab et al. (1999) and Takayama et al. The claims are interpreted as being drawn to various methods comprising administering a peptide comprising the sequence Tyr-Gly-Phe-Gly-Gly (SEQ ID NO:1; "YGFGG") to a subject or exposing cells to YGFGG. In some dependent claims, the subject has a myeloproliferative disorder, in some cases idiopathic myelofibrosis.

The teachings of Gurevitch et al. and Bab et al. (1999) are relied upon as discussed above. Gurevitch et al. and Bab et al. (1999) do not teach treating myeloproliferative disorders or specifically increasing circulating early CD34+ stem cells or colony forming units (CFUs) in subjects with myeloproliferative disorders.

Takayama et al. teach treating myeloproliferative disorders, including myelofibrosis, with an agent that promotes platelet and leukocyte production and reversing the damage to bone marrow caused by radiation therapy (column 12, Examples 1 and 2).

A person of ordinary skill in the art would have had a reasonable expectation of success in treating myeloproliferative disorders, including myelofibrosis, with the OGP of Gurevitch et al. because Gurevitch et al. teach that OGP stimulates bone marrow cell production and subsequent repopulation of the immune system (Table 3 and Figure 1).

The skilled artisan would have been motivated to so modify the invention for the expected benefit of treating myelofibrosis in a patient.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to treat myeloproliferative disorders, including myelofibrosis, with the OGP of Gurevitch et al. because Gurevitch et al. teach that OGP stimulates repopulation of the immune system and because Takayama et al. teach that such repopulation treats myeloproliferative disorders, including myelofibrosis.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Response to Arguments

Applicants rely on arguments traversing the above rejections under 35 U.S.C. § 102 to traverse this rejection (pages 23-25). Therefore, the response set forth above to arguments also applies to this rejection.

Furthermore, applicant provides a discussion of IFNγ and IL-3 as it pertains to Takayama (pages 24-25). However, Takayama was relied upon for teachings on the relationship between the treatment of myeloproliferative disorders and promotion of bone marrow health. There are no limitations in the claims that require "mobilization or particular enhancement of specific cell lineage," as asserted by applicant in the last paragraph of paragraph 25.

Double Patenting

The double patenting rejections of record are withdrawn unless specifically addressed below.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19, 26-28, and 46-48 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 20 of U.S. Patent No. 5,814,610, which shares six inventors with the instant application. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are all drawn to methods of administering the same peptide (YGFGG) to patients.

As discussed above in the rejections under 35 U.S.C. § 102, independent claims 19, 26, 28, 46, and 48 are drawn to methods of treating various hematological conditions and enhancing various hematological factors, *e.g.* the number of circulating stem cells, in "a subject in need thereof" by administering a peptide comprising YGFGG to the subject. Claim 20 of the '610 patent is drawn to a method of treating various

osteological conditions in a human or animal by administering to said human or animal a pentapeptide having the sequence YGFGG. Since all humans and animals (the scope of claim 20 of the '610 patent) require a healthy immune system, all humans and animals fall within the scope of "subject in need thereof" (the scope of many claims in the instant application). Therefore, the scope of claim 20 of the '610 patent is completely encompassed by the scope of the cited instant claims. The cited dependent claims in the instant application are included in this rejection because, as discussed at length above in the rejection under 35 U.S.C. § 102, they describe inherent effects of the administration of YGFGG and do not limit the method *per se* by requiring additional active process steps.

Applicant alleges that the claims in the instant application are restricted to subjects receiving irradiation or chemotherapy or suffering from hematological disorder (Remarks, page 26). However, the examiner notes for the record that claims 19, 26-28, and 46-48 have not been so amended. As discussed above in the art rejection under Chen, all that is required in these claims is the administration of YGFGG to cells (claim 19) or to a donor (claim 28) or to a mammal (claim 46) or to a subject (claim 48). Applicant is arguing limitations not recited in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

No claims are allowed. No claims are free of the art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should **specifically point out** the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SANDRA E. SAUCIER
PRIMARY EXAMINER

Lora E Barnhart